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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,103	02/14/2006	Kyle J. Lindstrom	58914US011	2609

32692 7590 09/15/2008
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PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
RAHMANI, NILOOFAR	
ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
09/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,103	LINDSTROM ET AL.	
	Examiner	Art Unit	
	NILOOFAR RAHMANI	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/09/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 15-62 are pending in the instant application and claims 1-14 are cancelled.

Priority

2. This application is filed on 02/14/2006, which is a 371 of PCT/US04/28021, filed on 08/27/2004.

3. *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-49, 56-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of binding of melanin concentrating hormone receptor, does not reasonably provide enablement for treat and prevent any and all diseases mediated by this receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the

level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims.
2) The nature of the invention,
3) The state of the prior art,
4) The level of one of ordinary skill,
5) The level of predictability in the art,
6) The amount of direction provided by the inventor,
7) The existence of working examples,
8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to method of inducing cytokine biosynthesis in an animal or a method of treating a neoplastic or viral disease in an animal comprising administering therapeutically effective amount of a compound or salt of claims 15, 27, 39, 50, 52.

The state of the prior art: " At the time that the invention was made, the scientific literature tends to show the speculative role of the cytokine and its role in the treatment of viral and neoplastic diseases. "Together our studies suggest that the immunosurveillance within the epithelium of the TZ may be intrinsically perturbed due to the altered expression of chemokines/ cytokines and the concomitant diminished density of LC. Furthermore, following HPV infection and the development of SILs, the function of LC may be further

incapacitated by viral associated mechanisms." (Emphasis added). Giannini Sandra et al., International journal of cancer. Journal international du cancer, (2002 Feb 10) Vol. 97, No. 5, pp. 654-9.

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the compounds of formula of claim 1 would be useful for treating a pharmacological condition in a subject.

Amount of guidance/working examples: Applicant provides examples of the test compounds to inhibit cytokine in vitro and vivo on pages 257-261 in the instant application. However, there is no guidance for using a therapeutically effective amount of the instant compounds to treat any and all viral or neoplastic diseases. Nor does applicant identify what diseases are treatable by therapeutically effective amount of the instant compounds.

The breadth of the claims: The breadth of claims is drawn to method of inducing cytokine biosynthesis in an animal or a method of treating a neoplastic or viral disease in an animal comprising administering therapeutically effective amount of a compound or salt of claims 15, 27, 39, 50, 52.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treating diseases associated with therapeutically effective amount of a compound of Formula (I), (III), (VII), (IX), (XI) is efficacious, one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claims 47-49, 56-62, for treating diseases associated with therapeutically effective amount of a compound of Formula (I), (III), (VII), (IX), (XI) is efficacious, have been enabled by the instant specification.

4. *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

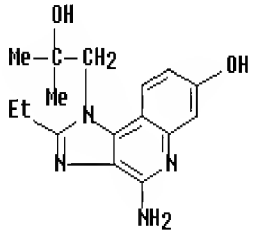
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

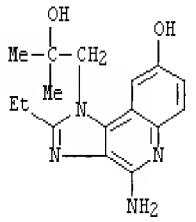
Claims 15-46, 50-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindstrom et al., WO 2005/0324846. Lindstrom et al. discloses the instant claimed compound, which from the STN search is

RN 1044004-27-4
CN 1H-Imidazo[4,5-c]quinoline-1-ethanol, 4-amino-2-ethyl-7-hydroxy-a,a-dimethyl-



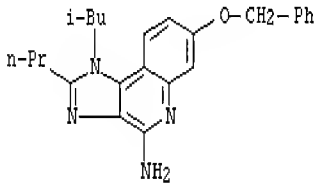
RN 1044005-37-9
CN 1H-Imidazo[4,5-c]quinoline-1-ethanol, 4-amino-2-ethyl-8-hydroxy-

a,a-dimethyl-



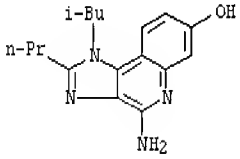
RN 847574-54-3

CN 1H-Imidazo[4,5-c]quinolin-4-amine, 1-(2-methylpropyl)-7-(phenylmethoxy)-2- propyl-



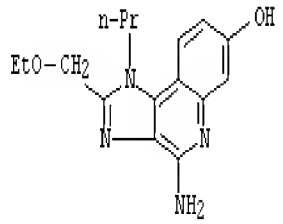
RN 847574-58-7

CN 1H-Imidazo[4,5-c]quinolin-7-ol, 4-amino-1-(2-methylpropyl)-2-propyl-



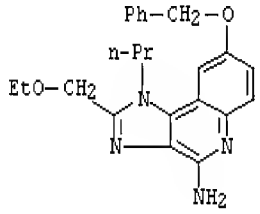
RN 847574-98-5

CN 1H-Imidazo[4,5-c]quinolin-7-ol, 4-amino-2-(ethoxymethyl)-1-propyl-



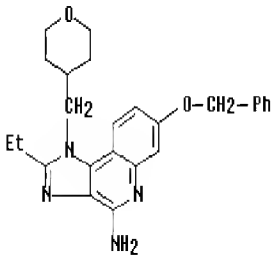
RN 847576-04-9

CN 1H-Imidazo[4,5-c]quinolin-4-amine, 2-(ethoxymethyl)-8-(phenylmethoxy)-1-propyl-



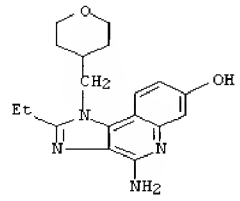
RN 850069-65-7

CN 1H-Imidazo[4,5-c]quinolin-4-amine, 2-ethyl-7-(phenylmethoxy)-1-[(tetrahydro-2H-pyran-4-yl)methyl]-



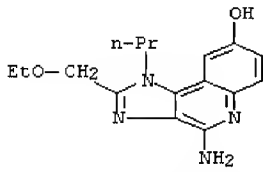
RN 850069-66-8

CN 1H-Imidazo[4,5-c]quinolin-7-ol, 4-amino-2-ethyl-1-[(tetrahydro-2H-pyran-4- yl)methyl]-



RN 850069-70-4

CN 1H-Imidazo[4,5-c]quinolin-8-ol, 4-amino-2-(ethoxymethyl)-1-propyl-



. Therefore, the instant claims are anticipated by Lindstrom et al.

5. *Claim Rejections - Obvious Double Patenting*

Claims 15-38, 46-49, 52-62 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 4-13, 23-49, 55-75, 78-79, 81-87, 89-111 of the Lindstrom et al., US 2007/0060754. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Lindstrom et al. claimed identical compounds and pharmaceutical composition in claims 4-13, 23-49, 55-75, 78-79, 81-87, 89-111 as the instant claims 15-38, 46-49, 52-62.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 4-13, 23-49, 55-75, 78-79, 81-87, 89-111 are therefore fully embraced by the instant claims 15-38, 46-49, 52-62.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1,1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 15-62 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-60 of the Griesgraberet al., US 7,163,947. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Griesgraber et al. claimed identical compounds and pharmaceutical composition in claims 1-60 as the instant claims 15-62.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 1-60 are therefore fully embraced by the instant claims 15-62.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

7. Claims 15-62 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-79 of the Griesgraberet al., US 2004/0176367. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Griesgraber et al. claimed identical compounds and pharmaceutical composition in claims 1-79 as the instant claims 15-62.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 1-79 are therefore fully embraced by the instant claims 15-62.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

8. *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* ***v.*** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

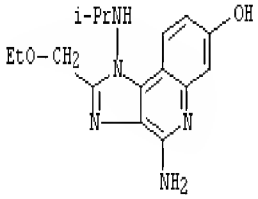
Claims 15-40, 42-46, 50-55 are rejected under 103(a) as being unpatentable over Griesgraber et al., US 7,163,947.

Determination of the scope and content of the prior art (MPEP §2141.01)

Griesgraber et al. disclosed analogous compounds, which from the STN search are

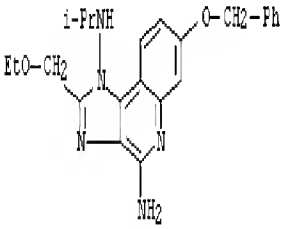
RN 749922-43-8

CN 1H-Imidazo[4,5-c]quinolin-7-ol, 4-amino-2-(ethoxymethyl)-1-[(1-methylethyl)amino]-



RN 749922-32-5

CN 1H-Imidazo[4,5-c]quinoline-1,4-diamine, 2-(ethoxymethyl)-N1-(1-methylethyl)-7-(phenylmethoxy)-



, wherein R^1 is –X-Y-R^4, wherein X being alkylene, Y being –N(R8)-Q-, and R4 being hydrogen, and Q being –C(R6)-C(R6)-.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claim and the prior art compound is that in the instant claims R1 has one mere methyl than the prior art claims.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the compounds of Griesgraber et al. to obtain the instant claimed compounds.

A compound that differs only in molecular arrangement from the compounds disclosed in the prior art and which for which no unexpected properties of this compound are disclosed in the specification is unpatenable, *Ex parte KRUEGER AND HAYES*, 121 USPQ 420, *In re NORRIS*, 84 USPQ 458, *In re Hass* 60 USPQ 552, which found a *prima facia* case of obviousness of 1-chloro-1-nitrobutane over 1-chloro-1-nitroisobutane taught in the prior art, *Ex parte Ullyot*, 103 USPQ 185, which found a *prima facia* case of obviousness of 2-oxo-quinolines over a 1-oxo-isoquinoline taught in the prior art, *In re FINLEY,* 81 USPQ 383 , which found a *prima facia* case of obviousness of 2-ethyl hexyl salicylate over octyl salicylate taught in the prior art.

Compounds that differ only by the presence or absence of an extra methylene group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologues. The homologue is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methylene groups. See *In re Wood,* 199 USPQ 137; *In re Hoke*, 195 USPQ 148, *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ; *In re Druey*, 138 USPQ 39.

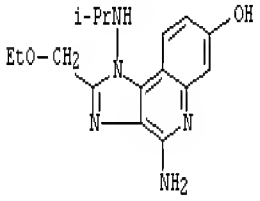
9. Claims 15-40, 42-46, 50-55 are rejected under 103(a) as being unpatentable over Griesgraber et al., US 2004/0176367.

Determination of the scope and content of the prior art (MPEP §2141.01)

Griesgraber et al. disclosed analogous compounds, which from the STN search are

RN 749922-43-8

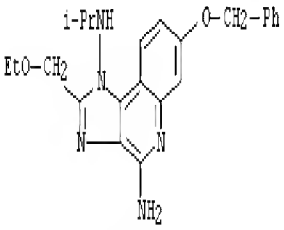
CN 1H-Imidazo[4,5-c]quinolin-7-ol, 4-amino-2-(ethoxymethyl)-1-[(1-methylethyl)amino]-



,

RN 749922-32-5

CN 1H-Imidazo[4,5-c]quinoline-1,4-diamine, 2-(ethoxymethyl)-N1-(1-methylethyl)-7-(phenylmethoxy)-



, wherein R^1 is –X-Y-R^4, wherein X being alkylene, Y being –N(R8)-Q-, and R4 being hydrogen, and Q being –C(R6)-C(R6)-.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claim and the prior art compound is that in the instant claims R1 has one mere methyl than the prior art claims.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the compounds of Griesgraber et al. to obtain the instant claimed compounds.

A compound that differs only in molecular arrangement from the compounds disclosed in the prior art and which for which no unexpected properties of this compound are disclosed in the specification is unpatenable, *Ex parte KRUEGER AND HAYES*, 121 USPQ 420, *In re NORRIS*, 84 USPQ 458, *In re Hass* 60 USPQ 552, which found a *prima facia* case of obviousness of 1-chloro-1-nitrobutane over 1-chloro-1-nitroisobutane taught in the prior art, *Ex parte Ullyot*, 103 USPQ 185, which found a *prima facia* case of obviousness of 2-oxo-quinolines over a 1-oxo-isoquinoline taught in the prior art, *In re FINLEY,* 81 USPQ 383 , which found a *prima facia* case of obviousness of 2-ethyl hexyl salicylate over octyl salicylate taught in the prior art.

Compounds that differ only by the presence or absence of an extra methylene group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologues. The homologue is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially,

the homologues are obvious even in the absence of a specific teaching to add or remove methylene groups. See *In re Wood,* 199 USPQ 137; *In re Hoke*, 195 USPQ 148, *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ; *In re Druey*, 138 USPQ 39.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NILOOFAR RAHMANI/

09/09/2008

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625